

The New Hampshire Department of Health and Human Services  
Committee for the Protection of Human Subjects

Full-Committee Review Checklist

Study Title: \_\_\_\_\_ CPHS# \_\_\_\_\_

Primary Investigator: \_\_\_\_\_

The submission for full-Committee Review must include the following materials:

For Full Committee Review (New Study):

- \_\_\_ A copy of the summary protocol in the NH CPHS format
- \_\_\_ A copy of any grant application or protocol for the same study submitted to the U. S. Department of Health and Human Services or FDA, if applicable;
- \_\_\_ A completed and signed Human Subjects Review Form
- \_\_\_ A copy of any applicable investigator's brochures
- \_\_\_ A copy of the consent form; in NH CPHS format
- \_\_\_ Letters of support from all sites under jurisdiction of the NH CPHS;
- \_\_\_ Copies of written materials used in the study and to which subjects might be exposed, such as assessment tools that are not standard, scripts, treatment manuals that are not standard, advertisements; or handouts.
- \_\_\_ Data Safety & Monitoring Board Plan (new submission)/Summary (renewals)

For Revision Requests:

- \_\_\_ A completed revision request form with signature and date (Department Chair or equivalent supervisor must sign if this increases risks)
- \_\_\_ A copy of the new or revised documents. If revised, then additions must be highlighted and deletions struck through.
- \_\_\_ A clean copy of revised documents.
- \_\_\_ If you are adding new sites, please include a letter of support for all sites under the jurisdiction of NH CPHS.

For Continuing Reviews (based on study status):

- The project did not start and is no longer in operation.
  - \_\_\_ Completed, signed and dated Continuing Review form
  - \_\_\_ In the progress report section of the Continuing Review form, describe the circumstances leading to this project not starting.
  - \_\_\_ Copy of Summary Protocol in CPHS format
- The project did not start but is expected to start during the next year.
  - \_\_\_ Completed, signed and dated Continuing Review form
  - \_\_\_ In the progress report section of the Continuing Review form, describe the circumstances leading to this project not starting or being delayed.
  - \_\_\_ A Human Subject Review Form (for studies that do not qualify for expedited review);

- ☐ A CPHS stamped copy of the consent (the one about to expire);
  - ☐ A clean copy of the consent form;
  - ☐ The sponsor protocol or NIH grant application (if applicable); and
  - ☐ A copy of the Summary protocol.
- The project is ongoing.
  - ☐ Completed, signed and dated Continuing Review form
  - ☐ In the progress report section of the Continuing Review form, provide enough detail for the Committee to understand the current status of the project
  - ☐ A Human Subject Review Form (for studies that do not qualify for expedited review);
  - ☐ A CPHS stamped copy of the consent (the one about to expire);
  - ☐ A clean copy of the consent form;
  - ☐ The sponsor protocol or NIH grant application (if applicable); and
  - ☐ A copy of the Summary protocol.
  - ☐ DSMB Summary (if applicable)
- The project is ongoing but closed to enrollment.
  - ☐ Completed, signed and dated Continuing Review form
  - ☐ In the progress report section of the Continuing Review form, provide enough detail for the Committee to understand the current status of the project
  - ☐ A Human Subject Review Form (for studies that do not qualify for expedited review)
  - ☐ The sponsor protocol or NIH grant application (if applicable),
  - ☐ A copy of the Summary protocol.
  - ☐ DSMB Summary (if applicable)
- The project concluded during the past year.
  - ☐ Completed, signed and dated Continuing Review form specifying the date the study ended
  - ☐ A Human Subject Review Form (for studies that do not qualify for expedited review);
  - ☐ A summary of the results;
  - ☐ The sponsor protocol or NIH grant application (if applicable); and
  - ☐ A copy of the Summary protocol.
  - ☐ DSMB Summary (if applicable)